k052303

DEC 16 2005

DailyCare Premarket Notification: Modification to ReadMyHeart

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1.0 Submitter's Indentification:

Submitter's Name:	DailyCare BioMedical Inc.
Address:	8F, 25-3, Ji-Lin Road, Chungli 320, Taiwan
TEL:	*+886-3-2621688*
FAX:	*+886-3-2617688*
Contact:	Mr. Daniel J. H. Chang

2.0 Device Name:

Trade Name:	ReadMyHeart
Common Name:	Handheld ECG monitor
Classification Name:	Electrocardiograph (per 21 CFR 870.2340)

3.0 Classification: Class II

4.0 Predicate Device: This predicate device is ReadMyHeart (k042814) marketed by DailyCare BioMedical Inc.

5.0 Intended Use:

ReadMyHeart OTC version is intended to record, store and transfer Lead I ECG signals, and display three ECG parameters for home health care use. The intended users are adults above 20 years old. This device is not intended to substitute for a hospital diagnostic ECG device. This device is also not intended for recording and transmission of user's ECG signal simultaneously. Users with implanted pacemaker are not recommended to use this device. The ReadMyHeart OTC version has simple software user interface without ECG trace viewing function.

6.0 Device Description:

ReadMyHeart is a handheld, personalized use, dry electrode and affordable ECG

recording device that records user's cardiac functions for daily health check. It takes ECG signals of users with thumbs press on electrode at ReadMyHeart gently. The device will record user's ECG signal for 30 seconds, and automatically stores the last 15 seconds signals into the build-in memory, while three parameters measured, mainly, Heart Rate (HR), ST segment and QRS interval of cardiac ECG signal, displays on LCD of the device.

User may also record ECG signals optionally through auxiliary external electrode provided separately, if thumb pressings are inconvenient for any reason. The data stored in the memory can be transferred to Personal Computer via USB. ReadMyHeart is powered by internal battery source. Users may activate the device to acquire ECG Lead I information voluntarily and mutually.

7.0 Performance Summary:

In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards include

* All Safety test according to IEC 60601-2-25 & IEC 60601-1,
* EMC tests according to IEC 60601-1-2
* Performance tests according to IEC 60601-2-47 and IEC 60601-2-51 voluntarily.
* Environment tests are tested to comply with the safety requirements.
*The performance is also tested with MIT-IBH database and simulators and meets the requirements.

8.0 Discussion of Clinical Test performed:

Since the ECG parameters algorithm and hardware design in this device is exactly the same as in the original cleared device, ReadMyHeart, no clinical validation for ECG parameters is required.

9.0 Conclusions:

In order to benefit the public health, the ReadMyHeart OTC version has simple software user interface without ECG trace viewing function. It has generally the same technological characteristics (e.g. circuit design and signal detection algorithm...) as original cleared ReadMyHeart. The OTC version demonstrates essential safety and effective to the common users.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

Dailycare Biomedical, Inc.
c/o Mr. Daniel J. H. Chang
Senior Engineer
8F, 25-3, Ji-Lin Road
Chungli 320
TAIWAN

Re: K052303
Trade Name: ReadMyHeart model RMH 2.0
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: November 18, 2005
Received: November 21, 2005

Dear Mr. Chang:

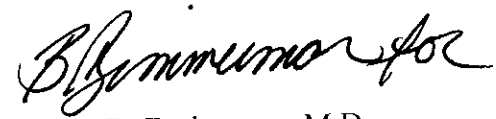
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052303

Device Name: ReadMyHeart
(DailyCare BioMedical Inc.)

Indications for Use:

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Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ✓
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052303